

CLAIMS

1. An introducer for positioning an expandable endovascular prosthesis (20) in a lumen of a patient, the prosthesis having a proximal portion and a distal portion, the introducer comprising; a prosthesis positioning mechanism (2, 3) selectively releasable from the prosthesis when the prosthesis is positioned at a desired site in the lumen of a patient; a first control member (22, 24) controlling at least the longitudinal position of the proximal portion of the prosthesis; and a second control member (44, 25) controlling at least the longitudinal position of the distal portion of the prosthesis.
2. The introducer according to claim 1, wherein said prosthesis positioning mechanism includes a distal attachment region (2) and/or a proximal attachment region (3).
3. The introducer according to claim 2, wherein said distal attachment region includes a distal attachment device (10).
4. The introducer according to claim 2 or 3, wherein said proximal attachment region includes a proximal attachment device (10).
5. The introducer according to any one of claims 1 through 4, wherein the prosthesis positioning mechanism comprises a control arrangement. (15, 41) for controlling the length of the prosthesis.
6. The introducer according to any one of claims 1 through 4, wherein the prosthesis positioning mechanism comprises a rotational arrangement (15, 41) by which the relative angular orientation of the proximal and distal portions of the prosthesis can be adjusted.
7. The introducer according to any one of claims 1 through 4, wherein the prosthesis positioning mechanism comprises a rotational arrangement (15, 41) by which the angular orientation of the prosthesis can be adjusted.
8. The introducer according to any one of claims 1 through 7, wherein the introducer further comprises an expansion control mechanism (10, 30) controlling expansion of the prosthesis when the prosthesis is positioned at

the desired site in the lumen of the patient.

9. An endovascular arrangement for positioning an expandable prosthesis at a desired location in a lumen of a patient, said arrangement comprising a control section (1) to be maintained external to the patient, and a prosthesis positioning mechanism (2, 3) controllable by the control section for moving and manipulating the prosthesis to a desired location in the lumen, wherein a first member (15) extends from the control section to a proximal region (3) of the positioning mechanism, the proximal region of the positioning mechanism having means (10) for controlling the proximal end of the prosthesis, wherein a second member (4) extends from the control section to a distal region (2) of the positioning mechanism, the distal region having means (40) for controlling the distal end of the prosthesis in cooperation with the second member.

10. The endovascular arrangement according to claim 9, wherein the arrangement further comprises contraction means for containing self expanding stents of the prosthesis during insertion of the prosthesis positioning mechanism into the lumen and/or expansion means for expanding expandable stents of the prosthesis when the prosthesis is positioned at the desired site in the lumen of the patient.

11. The arrangement according to claim 10, wherein the contraction means includes tubular means (30) that extends from the control section to the positioning mechanism and serves to contain the prosthesis during insertion of the positioning mechanism into the lumen and to control the distal end of the prosthesis when the tubular means has been moved in a distal direction relative to the first and second members, relative movement between the first and second members enabling manipulation of the prosthesis when in the lumen.

12. The arrangement according to claim 10 or 11, wherein the expansion means includes at least radial means for radially expandable stents of the prosthesis when the prosthesis is positioned at the desired location in the lumen.

13. The arrangement according to claim 12, wherein the expansion means includes an inflatable balloon.

14. The arrangement according to claim 12, wherein the first and second members are contained within the said tubular means.

15. The arrangement according to claim 12 or 14, wherein means (39) are provided for clamping the first and second members together during insertion of the prosthesis and for releasing the first and second members prior to the manipulation.

16. The arrangement according to claims 12, 14, or 15 wherein expansion of a non self expanding prosthesis can be performed by expansion of a balloon located around the first member and within the prosthesis, said balloon being inflatable from the control section.

17. The arrangement according to claim 12, 14, 15, or 16, wherein the said proximal region of the attachment mechanism contains tubular means (10) for containing the proximal end of the prosthesis prior to final positioning thereof, and wherein release of the prosthesis from tubular means (10) is achieved by proximal movement of the first member.

18. The arrangement according to any one of claims 9 through 17, wherein the second member has means (40) for controlling the distal end of the stent whilst the latter is inside the tubular means (30).

19. The arrangement according to any one of claims 9 through 18, wherein the arrangement further comprises release mechanisms (24, 25) in the control section for controlling wires (22, 44) extending to respective stents of the prosthesis.

20. The arrangement according to any one of the claims 9 through 19, wherein the prosthesis positioning mechanism comprises a control arrangement (15, 41) for controlling the length of the prosthesis.

21. The arrangement according to any one of claims 9 through 19, wherein the prosthesis positioning mechanism comprises a rotational arrangement (15, 41) by which the relative angular orientation of the proximal and distal portions of the prosthesis can be adjusted.

22. The arrangement according to any one of claims 9 through 19,

wherein the prosthesis positioning mechanism comprises a rotational arrangement (15, 41) by which the angular orientation of the prosthesis can be adjusted.

23. The arrangement according to any one of claims 9 through 19, wherein the introducer further comprises an expansion control mechanism (10, 30) for controlling expansion of the prosthesis when the prosthesis is positioned at the desired site in the lumen of the patient.

24. An introducer adapted for the introduction of a self expanding endovascular prosthesis into a lumen of a patient, the prosthesis having a proximal end and a distal end, the introducer comprising,

- a. a proximal attachment device adapted to be attached to the proximal end of the prosthesis,
- b. distal attachment device adapted to be attached to the distal end of the prosthesis,
- c. each of the proximal and distal attachment devices attaching to the prosthesis in such a manner that the prosthesis can be held in tension therebetween and that each end of the prosthesis can individually be moved in proximal and distal directions and be rotated, and
- d. proximal releasing means associated with the proximal attachment device and distal releasing means associated with the distal attachment device to enable selective releasing of the proximal and distal ends of the prosthesis.

25. An introducer as in claim 24 wherein the proximal attachment means has a long flexible extension on its proximal end to facilitate insertion of the introducer into a body lumen and its advancement along the lumen.

26. An introducer as in claim 25 wherein the proximal attachment device is mounted on a flexible thin walled tube which extends in a distal direction from the proximal attachment device to an external manipulation section of the introducer which is adapted to remain external of the patient.

27. An introducer as in claim 26 wherein the thin wall metal tube includes fluid connection means external of the patient to enable the introduction of a medical reagent therethrough.

28. An introducer as in claim 27 wherein the long flexible extension includes a hollow tube therethrough in fluid communication with the thin wall metal tube and a plurality of side holes to enable dispersion of the medical reagent proximal of the prosthesis.

5 29. An introducer as in claim 26 wherein the distal attachment device is mounted on a flexible thick walled tubing and coaxial on the thin walled tube and extending in a distal direction to the external manipulation section and mounted such that the respective tubes can be moved together or independently.

10 30. An introducer as in claim 29 including a haemostatic seal between the thin walled tube and the thick walled tube in the manipulation section.

31. An introducer as in claim 30 including means to introduce a medical reagent into an annular space defined between the thin walled tube and the thick walled tube.

15 32. An introducer as in claim 24 including a proximal trigger wire extending from the proximally attachment device to the manipulation section, the proximal trigger wire being adapted to activate the proximal releasing means.

20 33. An introducer as in claim 24 including a distal trigger wire extending from the distal attachment device to the manipulation section, the distal trigger wire being adapted to activate the distal releasing means.

25 34. An introducer as in claim 24 including an external release mechanism for each of the proximal trigger wire and distal trigger wire, the external release mechanism adapted to prevent accidental release of the trigger wires and to allow release of the distal releasing means only after release of the proximal releasing means.

35. An introducer as in claim 34 including a haemostatic seal around the respective trigger wires in the manipulation section.

30 36. An introducer as in claim 24 including an external sheath extending from external of the patient to cover and compress the prosthesis during

insertion of the introducer into a patient and movable longitudinally from outside the patient to expose the prosthesis.

37. An introducer as in claim 36 wherein the external sheath is coaxial with and a sliding fit on the thick walled tube.

5 38. An introducer as in claim 37 wherein the external sheath has a proximal end which is tapered and smoothed to present a low resistance to advancement of the introducer during insertion.

39. An introducer as in claim 36 wherein the proximal end of the external sheath is adapted to have a tight fit on to the proximal attachment device.

40. An introducer as in claim 24 wherein the distal attachment device is of a streamlined shape and is adapted to be advanced to the proximal attachment device whereby to allow smooth retrieval through the released prosthesis and into the external sheath for removal from a patient.

15 41. An introducer as in claim 24 wherein the prosthesis is a bifurcated prosthesis.

42. An introducer as in any one previous claim wherein the lumen of the patient is an aorta and the prosthesis is adapted to repair an aortic aneurism.

20 43. A method of placing a prosthesis into an internal lumen by means of an insertion assembly the method including the steps of:

a. inserting the insertion assembly including the prosthesis into the internal lumen,

b. withdrawing a sheath from the insertion assembly to expose the prosthesis,

25 c. releasing the prosthesis from the insertion assembly,

d. replacing the sheath onto the insertion assembly, and

e. retracting the insertion assembly.

30 44. A method as in claim 43 wherein the prosthesis has a proximal end and a distal end and the insertion assembly includes a proximal attachment device and a distal attachment device adapted to retain the proximal and

distal ends of the prosthesis respectively and the step of releasing the prosthesis includes the steps of releasing the proximal end and then the distal end.

5 45. A method as in claim 44 wherein the step of replacing the sheath onto the insertion assembly includes the step of advancing the distal attachment device up to the proximal attachment device and withdrawing the two devices together.

10 46. A method as in claim 44 wherein between steps (b) and (c) the prosthesis is manipulated by respective movements of the proximal attachment device and distal attachment device to correctly position the prosthesis.

15 47. A method as in claim 43 wherein the prosthesis is a bifurcated prosthesis and the step of withdrawing the sheath includes the steps of withdrawing the sheath to a first position in which a side arm of the prosthesis is exposed, insertion of an extension prosthesis into the side arm and then full removal of the sheath from the prosthesis.

48. A method as in claim 47 wherein the step of insertion of the extension prosthesis into the side arm comprises the steps of;

20 (f) inserting an extension insertion assembly into the side arm, the extension insertion assembly including a top guide mounted on a catheter, an extension prosthesis on the catheter and a sheath retaining the extension prosthesis and extending over the top guide,

(g) withdrawing the sheath to expose and deploy the extension prosthesis,

25 (h) withdrawing the sheath, top guide and catheter together.

49. A method as in claim 48 wherein the top guide includes a long proximal nose extension.

50. A method as in claim 48 wherein the catheter includes a distal stop and the extension prosthesis is mounted between the distal stop and the top

guide.

51. A method as in claim 43 wherein the prosthesis is a bifurcated prosthesis and the step of withdrawing the sheath includes the steps of withdrawing the sheath to a first position in which a first side arm of the prosthesis is exposed, insertion of a first extension prosthesis into the first side arm, then full removal of the sheath from the prosthesis to expose a second side arm and then insertion of a second extension prosthesis into the second side arm.

52. A method as in claim 51 wherein the step of insertion of the first extension prosthesis into the side arm comprises the steps of;

(f) inserting a first extension insertion assembly into the first side arm, the first extension insertion assembly including a top guide mounted on a catheter, an extension prosthesis on the catheter and a sheath retaining the extension prosthesis and extending over the top guide,

(g) withdrawing the sheath to expose and deploy the extension prosthesis,

(h) withdrawing the sheath, top guide and catheter together

and the step of insertion of the second extension arm includes the steps of ;s

(i) inserting a second extension insertion assembly into the second side arm, the second extension insertion assembly including a top guide mounted on a catheter, an extension prosthesis on the catheter and a sheath retaining the extension prosthesis and extending over the top guide,

(j) withdrawing the sheath to expose and deploy the extension prosthesis,

(k) withdrawing the sheath, top guide and catheter together..

53. A method as in claim 52 wherein each of the top guides includes a long proximal nose extension.

54 A method as in claim 52 wherein each of the catheters includes a distal stop and the extension prostheses are mounted between the distal stop and the top guide.

5 55. An intraluminal prosthesis having a tubular graft and a plurality of self expanding stents along the length of the graft the prosthesis having a proximal end and a distal end, the prosthesis being characterised by the stents at the proximal end and at the distal end being inside the tubular graft and the remainder of the stents being on the outside of the graft.

10 56. An intraluminal prosthesis as in claim 55 further including a further self expanding stent mounted to the proximal end of the graft and extending beyond the said proximal end.

57. An intraluminal prosthesis as in claim 56 when the further stent includes attachment devices.

15 58. An intraluminal prosthesis as in claim 57 wherein attachment devices comprise barbs extending towards the distal end of the prosthesis.

59. An intraluminal prosthesis as in claim 55 wherein the prosthesis is bifurcated at its distal end to provide a shorter prosthesis leg and a longer prosthesis leg.

20 60. An intraluminal prosthesis as in claim 55 wherein the shorter leg has a terminal stent on the outside of the prosthesis and the longer leg has the internal distal stent.

25 61. An intraluminal prosthesis as in claim 59 or 60 further including an extension prosthesis for insertion into the shorter prosthesis leg, the extension prosthesis comprising a tubular extension prosthesis and a plurality of self expanding stents, the extension prosthesis having a proximal end and a distal end, stents at the proximal and distal ends being inside the tubular extension prosthesis and the remaining stents being on the outside of the prosthesis.

30 62. An intraluminal prosthesis as in claim 56 wherein both the shorter leg and longer leg have external terminal stents and extension prostheses for

each leg, each extension prosthesis comprising a tubular extension prosthesis and a plurality of self expanding stents, the extension prosthesis having a proximal end and a distal end, stents at the proximal and distal ends being inside the tubular extension prosthesis and the remaining stents being
5 on the outside of the prosthesis.

63. An intraluminal prosthesis as in claim 55 wherein each stent is a zig-zag stent.